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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,515	11/28/2001	Shuqian Jing	00-659-A	1848
20306	7590	03/15/2004	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE SUITE 3200 CHICAGO, IL 60606			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

**Application No.**

09/995,515

**Applicant(s)**

JING, SHUQIAN

**Examiner**

Janet L. Andres

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,8,10,11,43-45,50,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,8,10,11,43-45,50,56 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/04</u> . | 6) <input type="checkbox"/> Other: _____  |

**RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 2 January 2004 is acknowledged. Claims 1, 4-8, 10, 43-45, 50, 56, and 57 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The objection to claim 50 is withdrawn in response to Applicant's amendment correcting the dependency.
4. The rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 as lacking enablement for the deposited material is withdrawn in response to the assurances of Applicant's representative on p. 17 of the response filed 2 January 2003.
5. The rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment removing the "hybridization" language.
6. The rejection of claims 1, 4-8, 10, and 43-45 under 35 U.S.C. 102(e) as anticipated by WO 01/92305 is withdrawn in response to Applicant's amendment limiting the scope of the claims.

***Claim Rejections Maintained/New Grounds of Rejection***

7. The rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. 101 as lacking utility is maintained for reasons of record in the office action of 26 June 2004.

Applicant argues that the application discloses that TGF- $\beta$ -R proteins share the greatest degree of similarity with GDF-3. Applicant argues that one of ordinary skill would recognize

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that the TGF- $\beta$ -R is a member of the TGF- $\beta$  family of proteins. Applicant further argues that, based on the expression profile, the artisan would recognize that the claimed molecules could be useful in, for example, regulating cell growth and development in prostate, testis, ovary, or liver.

Applicant's arguments have been fully considered but have not been found to be persuasive. As was stated on p. 4 of the office action of 26 June 2003, no function has been identified for GDF-3 and no receptor is known. Thus identification of the proteins as related to GDF-3 does not endow them with a utility. Furthermore, members of the TGF- $\beta$  family have diverse functions; they are involved in many different processes (Miyazano et al., cited in the previous office action). Thus the identification of a protein as being a member of this family does not endow it with a utility; there is no well-established utility associated with such an identification. The expression profile of the proteins does not serve to identify a function. Mere expression in different tissues does not indicate any particular activity. There is no nexus between expression in a tissue and a role in cell growth or development. In addition, the asserted utility of a "role" in growth or development does not indicate what that role is and thus how the proteins could be used.

8. The rejection of claims 1-4, 8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. 112, first paragraph, as lacking enablement because the invention lacks utility is maintained for reasons of record in the office action of 26 June 2003.

Applicant argues that because the application contains an assertion of a specific and substantial utility that one of ordinary skill in the art would find to be credible, the rejection should be withdrawn.

Applicant's arguments have been fully considered but have not been found to be persuasive. While the credibility of Applicant's assertions has not been challenged, for the reasons set forth above, Applicant's arguments with respect to the rejection of the claims under 35 U.S.C. 101 have not been found to be persuasive and, because the invention lacks utility, one of skill in the art would be unable to use it.

9. The rejection of claims 1-4, 8, 10, 11, 43-45, 50, 56, and 57 under 35 U.S.C. 112, as further lacking enablement for fragments and variants is maintained for reasons of record in the office action of 26 June 2003.

Applicant's cancellation of claims 2 and 3 is not sufficient to overcome this rejection because the claims still encompass molecules that are not identical to the disclosed sequence and that need have no function in common with the disclosed sequence.

10. The rejection of claims 1-4, 8, 10, 11, 43-45, 50, 56, and 57 under 35 U.S.C. 112, as lacking written description for fragments and variants is maintained for reasons of record in the office action of 26 June 2003.

Applicant's cancellation of claims 2 and 3 is not sufficient to overcome this rejection because the claims still encompass molecules that are not identical to the disclosed sequence and that need have no function in common with the disclosed sequence.

11. Claims 5 and 6 are newly rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Because the claims do not require that the host cells be isolated, they encompass cloned humans, which are non-statutory.

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NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
11 March 2004



JANET ANDRES  
PATENT EXAMINER